MEMORANDUM

TO: Health Care Clients and Friends
FROM: Chris Rossman, Honigman Miller Schwartz and Cohn
RE: Legal Issues Under Medicare Hospital Outpatient Prospective Payment System:
   - Provider-based Status
   - EMTALA
   - Interaction with Blue Cross Blue Shield of Michigan Guidelines
DATE: April 14, 2000

The Health Care Financing Administration (“HCFA”) published final rules (“Rules”) implementing the Medicare hospital outpatient prospective payment system (“PPS”) on April 7, 2000. Most providers are aware that the Rules implement an outpatient PPS based on ambulatory payment classification (“APC”) groups. However, many providers are not aware that the Rules have many other provisions that require providers to take affirmative actions. Further, the Rules make significant changes in the definition of provider-based status.

To avoid potential penalties for non-compliance, and to avoid unexpected reductions in Medicare payments, providers must carefully examine the provisions of the rules and take certain actions to protect their legal rights and Medicare payment levels.

Summary of Key Legal Issues Discussed in Memorandum

Following is a summary of the provisions of the Rules discussed in this Memorandum:

- Medicare criteria for determining whether facilities are provider-based or freestanding have changed. Free-standing facilities generally receive lower Medicare payments than provider-based facilities, even after APCs are implemented.

- In a departure from existing policy, providers will be required in many circumstances to apply for a HCFA determination that a facility is provider-based before it can be treated as provider-based on the cost report or for billing purposes.

- The risks to a provider of not requesting a HCFA determination that an existing facility is provider-based have increased significantly under the new Rules. A provider should perform an analysis of its existing facilities to determine whether they meet the new criteria, and whether to request HCFA to confirm the provider-based status of all existing facilities.
• Hospitals are required to use their privileging mechanisms to prevent inappropriate site-of-service indicators from being billed by physicians and practitioners in provider-based facilities.

• Blue Cross Blue Shield of Michigan standards for provider-based status are different than Medicare standards.

• New EMTALA protocols are required.

• Civil monetary penalties are imposed on a hospital for knowingly and willfully violating the outpatient unbundling prohibition; exclusion from Medicare may also be imposed as a penalty.

This Memorandum does not summarize all of the provisions of the Rules. It summarizes only those provisions that are the most significant from a legal perspective. There are many provisions of the Rules that are beyond the scope of discussion. For example, this Memorandum does not discuss special rules applicable to a community access hospital (“CAH”), rural health clinic (“RHC”) or federally qualified health clinic (“FQHC”). Nor does this Memorandum describe the APC payment system. For a complete understanding of the Rules, reference must be made to the Rules themselves.

**Provider-based Status Affects Level of Medicare Payments**

The most significant effect of the Rules is to change the approach that HCFA takes in dealing with provider-based entities. The rules are focused on whether or not a facility should be treated as integrated with the main provider. The rules generally provide that a facility is sufficiently integrated to attain provider-based status if it furnishes services under the name, ownership and administrative and financial control of the main provider.

Whether or not a facility is provider-based can have a significant effect on the level of payment that can be received for services provided at the facility:

1. A hospital can only bill for services under the new hospital outpatient PPS (i.e., on an APC basis) if the services were performed in the main provider or in a department of the provider. If the services were performed in a free-standing facility, a lower level of Medicare payment is generally available. Generally, a free-standing facility is eligible to receive only professional fees unless it can qualify as a provider of services in its own right.

2. Billings for professional services in the provider setting must contain the appropriate provider site-of-service indicator.

3. Payments under the Medicare hospital outpatient PPS (on an APC basis) can be received only by hospitals and hospital outpatient departments. If a facility is deemed to be free-standing, it cannot bill under the hospital outpatient PPS provisions.
4. Certain types of entities can receive higher Medicare payment rates if they are provider-based as opposed to free-standing.

**Key Definitions**

First, it is necessary to understand the terms used in the Rules:

1. A “main provider” is a provider into which the facility may or may not be integrated.

2. A “provider-based entity” is a provider of health care services that is deemed to be sufficiently integrated with the main provider and which furnishes health care services of a different type from those of the main provider. Examples include a skilled nursing facility (“SNF”) and a home health agency (“HHA”).

3. A “department of a provider” is a facility that:
   a. Furnishes health care services of the same type as those furnished by the main provider,
   b. Is not licensed to provide health care services in its own right, and
   c. Is not qualified to participate in Medicare as a provider.

4. A “free-standing facility” is a facility that furnishes health care services that is not integrated with any other entity.

5. “Provider-based status” means the relationship between a main provider and a department of a provider or provider-based entity. It also applies to remote locations of hospitals and satellite facilities.

**Situations Where Providers Must Request HCFA Determinations**

The Rules impose significant new obligations on providers to obtain determinations that their facilities are provider-based. Providers are required to obtain a HCFA determination that a facility is provider-based where it creates or acquires a new facility for which it wishes to claim provider-based status, including any physician offices that a hospital wishes to operate as a hospital outpatient department, if

a. The facility is located off the campus of the provider, or

b. Inclusion of the costs of the facility in the provider’s cost report would increase the total costs on the provider’s cost report by at least 5 percent.

“Campus”, as used in a. above, means the physical area immediately adjacent to the provider’s main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other
areas determined on an individual case basis, by the HCFA regional office, to be part of the provider’s campus.

A main provider must report to HCFA any material change in the relationship between it and any provider-based facility that could affect the provider-based status of the facility.

**Existing Facilities Currently Treated as Provider-based
May Lose that Status Retroactively**

The Rules create uncertainty regarding the status of existing facilities that a provider has been treating as provider-based for Medicare purposes. HCFA declined to explicitly require that a provider seek a HCFA determination that existing facilities are provider-based in order to be eligible for provider-based treatment. HCFA also declined to grandfather the prior treatment of such facilities as provider-based by the intermediaries, carriers or the HCFA regional office. Further, the Rules provide that HCFA has the right to retroactively review the status of facilities “in response to complaints or any other credible information that indicates that provider-based status requirements are not being met.”

In reviewing the status of a facility, HCFA will only apply the new Rules on and after October 10, 2000, the effective date of the provider-based provisions of the Rules. For periods prior to October 10, 2000, HCFA will apply the criteria in effect at the present time. These criteria can be found in Program Memoranda, the Provider Reimbursement Manual and State Operations Manual. The currently applicable criteria are significantly different than the criteria under the Rules. The current criteria are in general more lenient than the Rules in allowing a determination of provider-based status. Therefore, it is possible that a facility that was provider-based prior to the Rules would lose that status under the Rules. Because the criteria are different pre- and post-effective date, care must be taken in wording a request to HCFA for provider-based status to make sure that the desired result is obtained for both before and after the effective date of the Rules.

The Rules state that a prior determination that a facility was provider-based can be overturned by HCFA. If HCFA determines that a previous determination was in error, and the facility should not be considered provider-based, treatment of the facility as provider-based will cease with the first day of the next cost reporting period following notification of the redetermination, but not less than six months after the date of the notification.

However, if HCFA determines that a facility that has been treated by a provider as provider-based is not entitled to that status, and if no HCFA determination regarding provider-based status was previously made, then HCFA will retroactively recover the difference between provider-based and free-standing payments as far back as possible, unless the good faith exception (discussed below) applies. Generally, a cost report is open until three years after the date of the Notice of Program Reimbursement (“NPR”) issued with respect to the cost report.
Risks of Retroactive Revocation of Provider-Based Status

Several adverse consequences will occur if HCFA determines that a facility should not have been treated as provider-based. The most likely consequence is that HCFA will recover the difference between the amount actually paid and the amount that should have been paid in the absence of provider-based status. However, a recovery will not be made prior to October 10, 2000 if the provider made a good faith effort to operate it as a provider-based facility.

The good faith exception applies where:

a. The licensure and public awareness requirements of the Rules (discussed below) are met, and

b. All facility services are billed as if they had been furnished by a facility with provider-based status, and

c. All professional services of physicians and other practitioners are billed with the correct site-of-service indicator.

In addition to seeking to recover excess reimbursement, HCFA may seek more severe penalties for fraudulent billings if it finds that the provider knew or had reason to know that its facilities did not meet the requirements for provider-based status, and it nevertheless treated such facilities as provider-based for Medicare billing and cost reporting purposes. These penalties could include civil monetary penalties, Medicare exclusion and fines and imprisonment for commission of a federal felony.

The Rules Have Changed the Criteria for Determination that a Facility is Provider-based

The most significant change in the criteria for determining provider-based status is that the Rules state emphatically that the provider must meet all of the listed requirements. Under currently applicable guidelines, it has not been clear that all criteria have to be met, and there has appeared to be more discretion left to the HCFA regional office which makes the determination.

The following summarizes the requirements, all of which must be met to have provider-based status:

1. **Licensure.** The facility must be operated under the same license as the main provider, except where State law provides otherwise. In Michigan, facilities are not covered under the hospital license unless they are physically attached to the hospital.

2. **Operation under the ownership and control of the main provider.** The facility is operated under the ownership and control of the main provider.
3. **Administrative and supervision.** The reporting relationship between the facility and the main provider must have the same frequency, intensity and level of accountability that exists in the relationship between the main provider and one of its departments.

4. **Clinical services.** The clinical services of the facility and the main provider are integrated.

5. **Financial integration.** The financial operations of the facility are fully integrated within the financial system of the main provider, as evidenced by shared income and expenses between the main provider and the facility.

6. **Public awareness.** The facility is held out to the public and other payers as part of the main provider. When patients enter the facility, they are aware that they are entering the main provider and are billed accordingly.

7. **Location in immediate vicinity.** The facility and the main provider are located on the same campus (as defined above), or the following are meet:
   
   a. During the 12-month period immediately preceding the first day of the month in which the application for provider-based status is filed with HCFA, and for each subsequent 12-month period,
      
      i. At least 75 percent of the patients served by the facility reside in the same zip code areas as at least 75 percent of the patients served by the main provider, or
      
      ii. At least 75 percent of the patients served by the facility who required the type of care furnished by the main provider received that care from that provider, or
      
      iii. If the facility is unable to meet i. or ii. above because it was not in operation during all of the 12-month period, the facility is located in a zip code area included among those that, during all of the 12-month period, accounted for at least 75 percent of the patients served by the main provider.

The above summarizes the requirements for provider-based status. A detailed description of the requirements is set forth in Attachment A to this Memorandum.

An appeals process is provided if a provider is dissatisfied with the results of a HCFA determination regarding provider-based status.

**Requirements for Management Contracts**

To be provider-based, a facility operated under a management contract must have its non-management staff employed by the main provider or by another organization,
other than the management company, that also employs the staff of the main provider. The provider must have significant control over the operations of the provider, and the provider must hold the management contract.

**Joint Ventures Cannot be Provider-based**

A facility cannot be considered provider-based if it is owned by two or more providers engaged in a joint venture.

**Provider-based Status is Not Available Where All Services Are Provided Under Arrangements**

A facility may not qualify for provider-based status if all patient care services furnished by it are furnished under arrangement.

**Anti-dumping (EMTALA) Obligations**

Hospital outpatient departments located either on or off the campus of the hospital must comply with the anti-dumping rules. If any individual comes to any hospital-based entity located on the main hospital campus, and a request is made on the individual’s behalf for examination or treatment of a medical condition, the hospital must comply with the anti-dumping rules.

The definition of “comes to the emergency department” means that an individual is on hospital property. The Medicare regulations are clarified to provide that “property” means the entire main hospital campus (defined above) including the parking lot, sidewalk and driveway, and any facility that is located off the main hospital campus but is a department of the hospital.

The Rules add requirements for a department of a hospital located off the main hospital campus to comply with the EMTALA requirements. The hospital is not required to locate additional personnel or staff to off-campus departments to be on standby for possible emergencies. However, the hospital must establish protocols for the handling of individuals with potential emergency conditions at off-campus departments. These protocols must provide for direct contact between personnel at the off-campus department and emergency personnel at the main hospital campus and may provide for dispatch of practitioners, when appropriate, from the main hospital campus to the off-campus department to provide screening and stabilization services.

Provider-based entities, such as SNFs and HHAs, located off the hospital campus are not subject to EMTALA requirements.

The Rules contain significant detail regarding the new EMTALA requirements, including discussion of the contents of required protocols.
Billing Requirements

Physician services furnished in hospital outpatient departments or hospital-based entities must be billed with the correct site-of-service indicator. HCFA states that, while physicians are responsible for appropriate billings, physicians who practice in hospitals do so under privileges granted by the hospital. Therefore, hospitals have an obligation to ensure proper billing.

Hospital outpatient departments must treat all Medicare patients, for billing purposes, as hospital outpatients. The department must not treat some Medicare patients as hospital outpatients and others as physician office patients.

Advance Notice to Beneficiary of Financial Liability

When a Medicare beneficiary is treated in a hospital outpatient department or hospital-based entity that is not located on the main provider’s campus, the hospital has a duty to provide written notice to the beneficiary, prior to the delivery of services, of the amount of the beneficiary’s potential financial liability. The beneficiary will incur a coinsurance liability for an outpatient visit to the hospital as well as for the physician service. The Rules have detailed requirements for the content and giving of the notice.

Prohibition on Unbundling of Hospital Outpatient Services

Medicare Part B will not pay for any item or service that is furnished to a hospital outpatient during an encounter by an entity other than the hospital unless the hospital has an arrangement (as defined by Medicare regulations) with that entity to furnish that particular service to its patients. The following services are excluded from this prohibition:

- physician services
- physician assistant services
- nurse practitioner and clinical nurse specialist services
- certified nurse mid-wife services
- qualified psychologist services
- anesthetist services
- services furnished to SNF residents

Knowing and willful violation of this prohibition on unbundling hospital outpatient services will subject a hospital to civil monetary penalties of $2,000 per occurrence.

Blue Cross Blue Shield of Michigan (“BCBSM”) Criteria Are Different

A detailed discussion of BCBSM criteria for a determination of provider-based status is beyond the scope of this Memorandum. However, BCBSM applies a different rule for determining provider-based status. Generally, the BCBSM Participating Hospital Agreement (“PHA”) provides that services that come within the scope of the hospital’s license are covered services under the PHA, and that services that are not within the
scope of the hospital’s license are not covered services under the PHA. The most
reasonable interpretation of this provision is that a facility must be physically attached to
a building that is licensed by the Department of Community Health as a hospital to be
covered on the hospital’s cost report as a provider-based entity.

There have been a number of exceptions granted by BCBSM to this rule over the
years. However, the provision still applies in the PHA. Furthermore, BCBSM is
changing the way that it is paying for outpatient services by moving to a "community
pricing concept" for outpatient services. There will still be some differential in payment
based upon whether a facility is provider-based or free-standing in many circumstances,
however. Providers should carefully consider the BCBSM implications of this issue as
well as the Medicare implications.

BCBSM currently has an Evidence of Necessity ("EON") program in effect for
ambulatory surgery centers ("ASCs"). BCBSM is not granting any EONs for ASCs at
this time, based on its position that there is no need for ASCs anywhere in the State of
Michigan. On March 30, 2000, the Insurance Commissioner issued a report on the
BCBSM ASC provider class plan and will be requiring BCBSM to modify its ASC EON
criteria.
The most significant change in the criteria for determining provider-based status is that the Rules state emphatically that the provider must meet all of the listed requirements. In the prior guidance, it was not as clear that all criteria had to be met, and there appeared to be more discretion left to the HCFA regional office which makes the determination. The following summarizes the requirements for a determination of provider-based status:

1. **Licensure.** The facility must be operated under the same license as the main provider, except where State law provides otherwise. In Michigan, for example, most facilities will not have a hospital license unless they are physically attached to the hospital.

2. **Operation under the ownership and control of the main provider.** The facility is operated under the ownership and control of the main provider. The facility is 100 percent owned by the provider. The facility and the main provider have the same governing body and operate under the same organizational documents. The main provider has final responsibility for administrative decisions, final approval for contracts with outside parties, final responsibility for personnel policies and final approval for medical staff appointments in the facility.

3. **Administrative and supervision.** The reporting relationship between the facility and the main provider must have the same frequency, intensity and level of accountability that exists in the relationship between the main provider and one of its departments. All of the following must be met:
   a. The facility is under the direct supervision of the main provider.
   b. The facility is operated under the same monitoring and oversight by the provider as any other department of the provider, and is operated just as any other department of the provider with regard to supervision and accountability. The facility director:
      i. Maintains a reporting relationship with a manager at the main provider that has the same frequency, intensity and level of accountability that exists in the relationship between the main provider and its departments; and
      ii. Is accountable to the governing body of the main provider in the same manner as any department head of the provider.
   c. The following administrative functions of the facility are integrated with those of the provider:
- billing services
- records
- human resources
- payroll
- employee benefit package
- salary structure
- purchasing service

Either the same employees or group of employees handle these administrative functions for the facility and the main provider, or the administrative functions for both the facility and the provider are contracted out under the same contract arrangement, or handled under different contract agreements, with the contract of the facility being managed by the main provider.

4. **Clinical services.** The clinical services of the facility and the main provider are integrated as follows:

   a. Professional staff of the facility have clinical privileges at the main provider.

   b. The main provider maintains the same monitoring and oversight of the facility as it does for any other department of the provider.

   c. The medical director of the facility maintains a reporting relationship with the chief medical officer (“CMO”) of the main provider that has the same frequency, intensity and level of accountability that exists in the relationship between the medical director of a department of the main provider and the CMO, and is under the same type of supervision and accountability as any other director of the main provider.

   d. Medical staff committees or other professional committees at the main provider are responsible for medical activities in the facility or organization including quality assurance, utilization review and the coordination and integration of services, to the extent practicable, between the facility and the main provider.

   e. Medical records for patients treated in the facility are integrated into a unified retrieval system (or cross reference) of the main provider.

   f. Inpatient and outpatient services of the facility and the main provider are integrated, and patients treated at the facility who require further care have full access to all services of the main provider and are referred where appropriate to the corresponding inpatient or outpatient department or service of the main provider.

5. **Financial integration.** The financial operations of the facility are fully integrated within the financial system of the main provider, as evidenced by shared income
and expenses between the main provider and the facility. The costs of the facility are reported in a cost center of the provider, and the financial status of the facility is incorporated and readily identified in the main provider’s trial balance.

6. *Public awareness.* The facility is held out to the public and other payers as part of the main provider. When patients enter the facility, they are aware that they are entering the main provider and are billed accordingly.

7. *Location in immediate vicinity.* The facility and the main provider are located on the same campus (as defined above), or the following are meet:

   a. The facility demonstrates a high level of integration with the main provider by showing that it meets all of the other provider-based criteria, and demonstrates that it serves the same patient population as the main provider, by submitting records showing that, during the 12-month period immediately preceding the first day of the month in which the application for provider-based status is filed with HCFA, and for each subsequent 12-month period,

      i. At least 75 percent of the patients served by the facility reside in the same zip code areas as at least 75 percent of the patients served by the main provider, or

      ii. At least 75 percent of the patients served by the facility who required the type of care furnished by the main provider received that care from that provider, or

      iii. If the facility is unable to meet i. or ii. above because it was not in operation during all of the 12-month period, the facility is located in a zip code area included among those that, during all of the 12-month period, accounted for at least 75 percent of the patients served by the main provider.

   b. A facility is not considered to be in the “immediate vicinity” of the main provider unless the facility and the main provider are located in the same State or, where consistent with the laws of both States, adjacent States.

Note: Items 1. and 6. apply to departments of a provider but not to provider-based entities. Items 2., 3., 4., 5. and 7. apply to both departments of a provider and provider-based entities.